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Section XIV 510(k) Summary

April 14, 2003

A. Submitter's Name / Address

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B. Contact Person

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C. Device Name

Common Name:	Electrode, Electrosurgical, Patient Return
Trade Name:	Mega 2000 Soft Dual Cord Patient Return Electrode Pad
Classification (if known):	21 CFR 878.4400, Electrosurgical cutting and coagulation device and accessories

D. Predicate Device

Mega 2000® Soft Patient Return Electrode Pad manufactured by Megadyne (K021077).

E. Applicant Device Description

The Mega 2000 Soft Dual Cord is constructed of a layer of conductive material strain-relieved with two sheets of urethane material, and sealed between two asymmetric layers of a viscoelastic polymer. (The top layer of polymer is thinner than the bottom layer.) The polymer is encapsulated by a layer of urethane film. Two cables connect the conductive layer of the device to two DetachaCables™. The DetachaCable(s) are connected to a standard monopolar electrosurgical unit (ESU). The device cables are insulated and strain-relieved well inside the device to prevent patient or user burns.

The device is large enough to extend at least the length and width of a typical patient torso. Pad size is approximately 20" x 46" x ½".

In use, this device will lay on an operating room table with the patient lying on top, on the side labeled "patient side".

F. Applicant Device Intended Use

The Mega 2000 Soft Dual Cord Patient Return Electrode Pad is to be used as a general purpose return electrode for one or two electrosurgical generators and/or a pressure reduction pad in any surgical application. Electrosurgical use is restricted to use with isolated monopolar electrosurgical generators.

G. Technological Characteristics

The technological characteristics of the proposed device are similar to the predicate device. The only difference is the addition of a second cord for connection to two different electrosurgical units at the same time during a procedure. Other technological characteristics (capacitive coupling and pressure reduction) are identical to the predicate device.

H. Safety Information

The only current flow from the patient to the Mega2000 Soft Dual Cord Patient Return Electrode Pad is via capacitive coupling. This device is designed to be current limiting (<100 mA/cm^2) so as to prevent the patient from getting return electrode site burns. This current limiting attribute is achieved by selecting materials with high impedance per area.

The large contact area between the electrode and the patient lowers the total impedance when there is substantial patient / pad contact area, and allows for enough current flow for electrosurgery to be performed at the surgical site(s).

Prior to release of the device for distribution, Megadyne conducted extensive testing of the device to assure its conformance to the voluntary standard ANSI /

AAMI HF 18-2001, *Electrosurgical Devices*. The clauses of the standard which apply to capacitively-coupled return electrodes are:

Maximum Safe Temperature Rise:
Maximum Safe Temperature Rise was demonstrated, using the method specified by the standard, with human volunteers and two electrosurgical generators. The device is well within the requirements of the standard. (Ref. Appendix A.)

Electrode Contact Impedance:
Conformance with the minimum capacitance requirement was demonstrated through bench testing. Device capacitance was evaluated under several different test setups intended to simulate clinical use. (Ref. Appendix B.)

Both proposed and predicate device performed similarly during the above testing. This device conforms to the applicable sections of AAMI HF-18/2001, under test conditions. However, as with the predicate device, field conformance is affected by clinical set-up which is beyond Megadyne's control.

*I. **Megadyne's Manufacturing Facility***
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Section XV Appendix A: Mega2000 Soft Dual Cord Temperature Rise Test

Document Number: X1150075-03
Authored By: Doug Orr
Eng. Approval: Doug Orr
QA Approval: Ihsan Samara

ABSTRACT

Mega2000® Soft Dual Cord reusable return electrodes were tested per the requirements of protocol X1150075-10 revision 3. This testing was performed to ensure compliance with the requirements in ANSI/AAMI HF-18, paragraph 4.2.3.1. An infrared camera was used to record the temperature changes. The samples were tested in accordance with the IFU, specifically with no linen between the pad and the patient and with a single linen layer between the pad and the patient. The results show that the requirements of ANSI/AAMI HF-18,

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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MAY 1 9 2003

Ms. Ronda K. Magneson
Manager, Regulatory Affairs
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Megadyne Medical Products, Inc.
11506 South State Street
Draper, Utah 84020

Re: K031285
Trade/Device Name: Mega 2000 Soft Dual Cord Patient Return Electrode Pad
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: April 14, 2003
Received: April 23, 2003

Dear Ms. Magneson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section IV Indications for Use Statement

510(k) Number (if known): K031285

Device Name: Mega 2000® Soft Dual Cord Patient Return Electrode Pad

Indications for use:

The Mega 2000 Soft Dual Cord Patient Return Electrode Pad is to be used as a general purpose return electrode for one or two electrosurgical generators and/or a pressure reduction pad, in any surgical application. Electrosurgical use is restricted to use with isolated monopolar electrosurgical generators.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K031285

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)